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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of Spear *et al.* :
: Art Unit 1643
Serial No.: 08/509,024 :
: Examiner:
Filed: July 28, 1995 : D. Lee
: Attorney Docket
For: HERPES VIRUS ENTRY RECEPTOR :
PROTEIN : No. 0290-1 (10147-1)

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AMENDMENT

This Amendment is being filed in response to the Office Action dated December 21, 1998 (Paper No. 28), issued in connection with the above-identified application. This Amendment is being timely filed in view of the accompanying Petition for a two month extension of time, which extends the time for a response to the Office Action through and to May 21, 1999. In response to the Office Action, kindly amend the application as follows.

In the Specification:

Please amend the specification as set forth below.

On page 32, on line 12, please insert ~~--97236--~~ before (pBEC580), please insert ~~--97235--~~ before (pBEC10), and on line 12, please insert ~~--97237--~~ before (pBL58).

Please delete the Sequence Listing filed with the Supplemental Amendment dated October 2, 1998, and replace it with the accompanying Substitute Sequence Listing.

In the Drawings:

Please delete the present Figure 2 in the application and replace it with the accompanying Figure 2.

Please insert the accompanying Figure 8 into the application and renumber Figures 8 and 9 (prior to this insertion) as Figures 9 and 10, respectively.

7

In the Claims:

Please amend claims 28, 29, 30 and 46 as follows:

E² 1 ~~28~~. (Twice amended) An isolated polynucleotide comprising a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.

E³ ~~29~~ (Amended) The isolated polynucleotide sequence of ~~claim 28~~ wherein said cDNA is the sequence of SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142.

E⁴ ~~30~~ (Twice amended) An isolated polynucleotide complementary to a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.

E⁵ ~~46~~ (Amended) A plasmid selected from the group consisting of pBEC10 (ATCC No. 97235), pBEC580 (ATCC No. 97236) and pBL58 (ATCC No. 97237).

(Please add the following new claims, claim 47-51.)

sub E⁶ ~~47~~. An isolated polynucleotide comprising a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said polynucleotide further comprises a rabbit immunoglobulin heavy chain nucleotide sequence.

E⁶ ~~48~~. An isolated polynucleotide comprising a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said cDNA comprises a nucleotide sequence which encodes soluble HVEM and does not comprise a nucleotide sequence which encodes rabbit immunoglobulin heavy chain.

~~49~~. An isolated polynucleotide comprising a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said cDNA encodes amino acids 1-185 of human HVEM.

sub E⁵ 50. An isolated polynucleotide comprising a nucleotide sequence which a) encodes soluble HVEM, wherein said soluble HVEM comprises an amino acid sequence encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237); and b) does not encode a rabbit immunoglobulin heavy chain amino acid sequence.

~~51~~. An isolated polynucleotide comprising at least 50 contiguous nucleotides of the HVEM cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.--

In the Supplemental Amendment filed on October 2, 1998:

On page 2, please delete lines 22 and 23 which state "Asterisks show the positions of amino acids that are highly conserved in the family. The arrow after Cys185 indicates the last amino acid of HVEM present in the fusion protein, HVEM:Fc."

On page 2, line 25, please disregard the instructions to delete lines 1-9 on, page 6 of the specification, and please reinsert original lines 1-9 of the original specification into the application at page 6, lines 1-9. In other words, please return the specification to its original form on page 6, lines 1-9.

On page 2, lines 26 and 27, please disregard the instructions to delete "9" and insert --8-- in place thereof on page 6, line 11 of the original specification. Please also disregard the instructions to delete "10" and insert --9-- in place thereof on page 6, line 19 of the original specification. In other words, please return the specification to its original form on page 6, lines 11 and 19.

On page 3, lines 10 and 11, please disregard the instructions to delete "(See SEQ ID NO:6, FIGs. 8A and 8B" and to insert --(FIG. 7)-- in place thereof on page 23, line 20 of the original specification. Please also disregard the instructions to delete "FIGs. 8A and 8B" on page 23, lines 21 and 22 of the original specification. In other words, please return the specification to its original form on page 23, lines 20 to 23.

REMARKS

Claims 28-51 are pending in the present application.

Claims 28, 29, 30 and 46 have been amended to add ATCC Accession Numbers and in the case of claim 29, to correctly depend from claim 28. These amendments do not constitute new matter.

New claims 47-51 have been added by way of the present amendment. Claim 47 is drawn to a polynucleotide comprising a cDNA encoding a portion of human HVEM fused to a polynucleotide encoding a rabbit immunoglobulin heavy chain nucleotide sequence, the polynucleotide being contained within plasmid pBL58. Claims 48 and 50 are drawn to a polynucleotide comprising a cDNA encoding a portion of HVEM, which polynucleotide does not

comprise the immunoglobulin sequences in the plasmid pBL58. Claim 49 is specifically directed to a polynucleotide encoding amino acids 1-185 of human HVEM. Claim 51 is directed to an isolated polynucleotide comprising at least 50 contiguous nucleotides of the HVEM cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.

Support for the addition of these claims is found in the specification in Figure 8, in the description of Figure 8 on page 6 and the actual Figure 8, wherein there is provided the nucleotide sequence of the claimed portion of human HVEM, and the nucleotide sequence encoding the rabbit immunoglobulin heavy chain. Upon a reading of the description of Figure 8 on page 6, and upon inspection of the actual Figure, it is clear that the portion of the human HVEM polynucleotide in pBL58 which encodes HVEM, but does not encode any immunoglobulin sequences encodes amino acids 1-185 of human HVEM. Further, a polynucleotide encoding soluble HVEM is disclosed in the specification on page 22, lines 16-20, and a recitation that HVEM is encoded by a polynucleotide comprising at least 50 nucleotides is found in the specification on page 10. Thus, not new matter has been added by way of the addition of claims 47-51.

In the Office Action, the Examiner has requested that the ATCC Accession Number for plasmids pBEC10, pBEC580 and pBL58 be inserted on page 32. Applicants have complied with this request. These amendments do not constitute new matter under the meaning of 35 U.S.C. § 132 as they merely serve to provide ATCC Accession Numbers for plasmids deposited therein, which plasmids are fully described in the specification as-filed.

The Examiner has objected to the disclosure because the term --HVEM-- should be inserted in place of the term "HVER" on page 7, line 2 and page 22, line 29. Applicants respectfully point out that --HVEM-- replaces "HVER" in the specification at the designated locations per the Supplemental Amendment filed on October 2, 1998 (see page 1, last paragraph, line 4 and page 2, line 2 of the Supplemental Amendment). Thus, with respect to this point, the specification has not been amended further in the present Amendment.

The Examiner has also objected to the Amendment filed on October 2, 1998, because, in the Examiner's view, the Amendment introduces new matter. Specifically, the Examiner has objected to the amendment to Figure 2 with respect to the statement "asterisks

show the position of amino acid" This statement has been deleted in the present Amendment. In addition, Applicants hereby submit a substitute Figure 2 which is identical to the Figure 2 added by way of the Supplemental Amendment filed on October 2, 1998, except that the asterisks and the arrow have been deleted therefrom. Thus, the objection to the Amendment filed on October 2, 1998 should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 28-46 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner is unclear as to what sequence is in which plasmid. Applicants direct the Examiner's attention to the specification on page 14, lines 21 to 30, wherein it is disclosed that the sequence in pBL580 is that shown in Figure 2 of the application, i.e., SEQ ID NO:1. On page 16 of the specification, lines 11-19, it is disclosed that the sequence in the plasmid pBEC10 is also that shown in Figure 2, i.e., SEQ ID NO:1. Essentially, the HVEM sequence contained with pBEC580 was recloned into the vector pcDNA3, thereby generating the plasmid pBEC10. Thus, the HVEM sequence in pBEC580 and pBEC10 are the same. The plasmid pBL58 contains DNA encoding the soluble portion of HVEM (SEQ ID NO:6 is the DNA sequence and SEQ ID NO:7 is the amino acid sequence of this portion of HVEM) fused to an Fc molecule as disclosed in Figures 7 and 8 and on pages 22 and 23 of the specification. Since the sequences contained within the various plasmids are clear from a reading of the specification, no claim amendments are necessary.

In addition, the Examiner has requested that the claims be amended to include the relevant ATCC numbers for the plasmids recited therein. Claims 28, 30 and 46 have been so amended.

The Examiner also states that claim 46 is confusing, in that, the claim recites the plasmid pBL58, and, in view of the fact that Figure 8 was canceled in the Amendment filed on October 2, 1998, the Examiner asks whether Applicants intended to remove all reference to pBL58 from the specification. In response, Applicants point out that this was not the intent, and that further, a description of the plasmid pBL58 remains in the specification in Figure 7.

Notwithstanding the foregoing, in the present Amendment Applicants include a substitute Figure 8, which contains the sequence of pBL58 (ATCC No. 97237) as deposited with

the ATCC on the filing date of the present application. The sequence shown in substitute Figure 8 does not constitute new matter, in that it is identical to that contained in deposited plasmid pBL58. As stated in the accompanying Declaration of Dr. Spear, a co-inventor of the present application, the sequence provided in substitute Figure 8 and in the substitute sequence listing which also accompanies this Amendment, is the sequence of the HVEM DNA contained within the plasmid pBL58 deposited with the American Type Culture Collection. Thus, substitute Figure 8 and SEQ ID NOS:6 and 7 are enabled by the as-filed specification and the claims therefore satisfy the enablement requirement of 35 § 112, first paragraph.

The written description requirement of 35 U.S.C. § 112, first paragraph, is also satisfied in view of the fact that claim 46 recites pBL58, pBL58 is described in the specification on pages 22 and 23, and a diagram of pBL58 is provided in as-filed Figure 7. Thus, the specification satisfies the written description requirement with respect to plasmid pBL58 and any nucleotide sequence of HVEM contained therein.

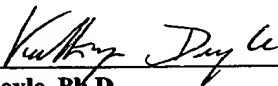
In view of the foregoing, Applicants respectfully submit that claims 28-46 are in condition for allowance and such action is respectfully and earnestly requested.

Respectfully submitted,

SPEAR ET AL.

May 20, 1999
(Date)

By: _____


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Enclosures: New Figure 2
New Figure 8
Sequence Listing (Paper and Diskette Copy)
Statement to Support Filing
Declaration of Dr. Spear
A Supplemental IDS and PTO Form 1449
A Petition for a two month extension of time.

KDL/moh

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MONTGOMERY, Rebecca I.

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 195 200 205
 Gly Pro Ser Val Phe Ile Phe Pro Pro Lys Pro Lys Asp Thr Leu Met
 210 215 220
 Ile Ser Arg Thr Pro Glu Val Thr Cys Val Val Val Asp Val Ser Gln
 225 230 235 240
 Asp Asp Pro Glu Val Gln Phe Thr Trp Tyr Ile Asn Asn Glu Gln Val
 245 250 255
 Arg Thr Ala Arg Pro Pro Leu Arg Glu Gln Gln Phe Asn Ser Thr Ile
 260 265 270
 Arg Val Val Ser Thr Leu Pro Ile Thr His Gln Asp Trp Leu Arg Gly
 275 280 285
 Lys Glu Phe Lys Cys Lys Val His Asn Lys Ala Leu Pro Ala Pro Ile
 290 295 300
 Glu Lys Thr Ile Ser Lys Ala Arg Gly Gln Pro Leu Glu Pro Lys Val
 305 310 315 320

Tyr Thr Met Gly Pro Pro Arg Glu Glu Leu Ser Ser Arg Ser Val Ser
325 330 335

Leu Thr Cys Met Ile Asn Gly Phe Tyr Pro Ser Asp Ile Ser Val Glu
340 345 350

Trp Glu Lys Asn Gly Lys Ala Glu Asp Asn Tyr Lys Thr Thr Pro Ala
355 360 365

Val Leu Asp Ser Asp Gly Ser Tyr Phe Leu Tyr Asn Lys Leu Ser Val
370 375 380

Pro Thr Ser Glu Trp Gln Arg Gly Asp Val Phe Thr Cys Ser Val Met
385 390 395 400

His Glu Ala Leu His Asn His Tyr Thr Gln Lys Ser Ile Ser Arg Ser
405 410 415

Pro Gly Lys